Remarks

Claims 1-9 and 11-21 were pending in the subject application. By this Amendment, claims 12 and 13 have been amended and claims 14 and 16-21 have been cancelled. Support for these amendments can be found throughout the specification and claims as originally filed. No new matter has been added by these amendments. Accordingly, claims 1-9, 11-13 and 15 are now pending in the subject application and before the Examiner for consideration.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be taken to indicate the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 12-21 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The applicants respectfully traverse this ground for rejection to the extent that it might be applied to the claims now presented for examination.

Please note that the claims have been amended herein to provide greater clarity to the claimed subject matter by focusing these claims on the treatment of certain specific conditions. The Office Action indicates that the specification does not provide "conclusive evidence" that the claimed compounds could be used for treating and preventing all diseases associated with GnRH. While the applicants do not agree that "conclusive evidence" is required to meet the written description requirement of 35 U.S.C. §112, first paragraph, they have endeavored herein to expedite prosecution by limiting their claims only to the treatment of certain conditions that were acknowledged in the Office Action as being recognized by those skilled in the art as being associated with GnRH.

The test for an adequate written description has been stated in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under Vas Cath, Inc. *v.* Mahurkar, 935 F.2d 1555, 1563?64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those

skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. It is respectfully submitted that the applicants have met this test given the teachings of the specification and the scope of the claims.

Accordingly, the applicants respectfully request reconsideration and withdrawal of the "written description" rejection under 35 U.S.C. §112, first paragraph.

Claims 12-21 have been rejected under 35 U.S.C. §112, first paragraph, under the enablement requirement. The applicants respectfully traverse this ground for rejection to the extent that it might be applied to the claims now presented for examination. Specifically, the applicants respectfully submit that a person skilled in the art could readily, and without undue experimentation, practice the full scope of the claims that are now presented for examination.

As noted above, the claims have been amended herein to expedite prosecution by focusing on the treatment of conditions that were specifically noted in the Office Action as being associated with GnRH.

It should be noted that the requirement for some experimentation and/or screening does not necessarily make a claim non-enabled. "Enablement is not precluded by the necessity for some experimentation such as routine screening. . . A considerable amount of experimentation is permissible, if it is merely routine . . ." (emphasis added). *In re Wands,* 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988). In the current case, any experimentation needed would be routine given the guidance provided in the subject application.

It is important to bear in mind that for an invention to be enabled under the first paragraph of §112, the specification need only teach a person of ordinary skill in the art "how to make" and "how to use" the invention. The applicants are cognizant of the duty under §112, first paragraph, to provide sufficient teaching in the specification to enable one skilled in the art to practice the invention as claimed without undue experimentation.

A person of ordinary skill in this art could readily and without undo experimentation practice the methods as now claimed by the current applicants. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Claims 1-9 and 11-21 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson *et al.* (WO 2000/020358), in view of King (Med Chem: Principle and Practice (1994), pages 206-209). The applicants respectfully traverse this ground for rejection because the cited references, taken either alone or in combination, do not disclose or suggest the claimed subject matter.

As the Examiner noted in the outstanding Office Action, the treatment of cancer and other disorders related to GnRHcan be very unpredictable. Thus, it is only through the results of empirical research that it can be known whether analogs, modifications and/or variants of known compounds will have the same (or better) activity in a physiological system. Thus, the cited references, which certainly do not teach the applicants' modified compounds cannot be said to make these new compounds obvious in the context of an unpredictable physiological system.

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless "there was an apparent reason to combine the known elements in the fashion claimed" by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___ (2007). Furthermore, an applicant's invention is not "proved obvious merely by demonstrating that each of its elements was, independently, known in the (purported) prior art." *Id.*

A finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. Here, it is only the applicants' disclosure that provides such a teaching, and applicant's disclosure cannot be used to reconstruct the prior art for a rejection under §103. This was specifically recognized by the CCPA in *In re Sponnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

> The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Sprock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

Furthermore, as expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art ..." *In re Dow Chemical Co.* 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). One finds neither the suggestion nor the expectation of success in the cited references, either separately or combined. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103.

In view of the foregoing remarks and the amendment above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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